CONCLUSIONS: Resource utilization and costs associated with migraine increased with greater headache frequency. Treatments that reduce headache frequency have the potential to have a positive economic impact by reducing costs associated with migraine care.

PND33

UTILIZING A PAPER STANDARD GAMBLE INSTRUMENT TO ASSESS HEALTH UTILITY IN PATIENTS WITH HEMOPHILIA B

Lou M[1], Zhou ZY[1], Gwadry-Sridhar F[2], Poon JL[1], Doctor J[1], Koerper M[3], Ullman M[4], Johnson K[1]
[1]*USC School of Pharmacy, Los Angeles, CA, USA,* [2]*University of Western Ontario, London, ON, Canada,* [3]*UCSF HTC, San Francisco, CA, USA,* [4]*University of Texas Health Science Center at Houston, Houston, TX, USA*

OBJECTIVES: To conduct a pilot study examining the validity and reliability of a paper-based standard gamble (PSG) instrument and to administer the validated PSG among persons with hemophilia B enrolled in the Hemophilia Utilization Group Study (HUGS-Vb). **METHODS:** Fifteen pharmacy students were enrolled in this pilot. We presented a hypothetical scenario describing a patient with severe hemophilia to each participant, followed by three tests: (1)Standard Gamble (SG) using the probability wheel, (2)PSG and (3)Visual Analog Scale (VAS), each administered in random order. PSG was re-administered after two weeks to assess test-retest reliability. The validated PSG was subsequently administered to participants enrolled in HUGS-Vb, a prospective, multicenter study collecting utilization and other data associated with hemophilia B in the United States. Participants or their parent(s) completed a demographic questionnaire, the PSG and the EQ-5D. A PSG scenario based on actual demographic and clinical characteristics was created for each participant. Paired t-test, Spearman rank correlation coefficient (rho) and intra-class correlation coefficient (ICC) were used to assess the convergent validity and reliability of the instrument. **RESULTS:** Mean SG, PSG and VAS in the pilot were 0.79±0.15, 0.82±0.14 and 66.8±23.0, respectively. The mean difference between PSG and SG did not differ significantly from 0 (p=0.124). PSG was significantly correlated with SG (rho=0.769, p=0.0008) and VAS (rho=0.534, p=0.0405). PSG re-test score was 0.79±0.13 and test-retest ICC was 0.85 (95% CI: 0.63-0.94; p<0.0001). Of 71 HUGS-Vb participants, 32 (45%) were adults; 38 (54%) had severe hemophilia. Mean age was 21.8 years (range 2-61). Mean PSG and VAS scores were 0.91±0.15 and 84.4±14.6 respectively, with weak correlation between the two (rho=0.242, p=0.0452) in the full sample. Adult PSG and EQ-5D scores were 0.87±0.18 and 0.85±0.16 respectively, with correlation rho=0.348 (p=0.0506). **CONCLUSIONS:** A paper-based standard gamble instrument may be a valid, reliable alternative to SG for measuring health utility in hemophilia patients.

PND34

MAPPING THE INSOMNIA SEVERITY INDEX (ISI) TO THE EQ-5D UTILITIES

Gu NY[1], Ji X[1], Bell C[2], Botteman M[1]
[1]*Pharmerit North America, LLC, Bethesda, MD, USA,* [2]*GlaxoSmithKline, Research Triangle Park, NC, USA*

OBJECTIVES: To map the Insomnia Severity Index (ISI) to the EQ-5D utilities. **METHODS:** A cross-sectional, online survey was conducted among adult US residents with self-reported sleep problems. Respondents provided demographic, co-morbidity, previous-night sleep-related information and, completed the EQ-5D and the ISI, a seven-item instrument measuring perceived insomnia severity. Each ISI item is scored from 0-4 with minimum total score of 0 (no insomnia) and a maximum of 28 (most severe insomnia). Respondents can be classified into four ISI categories (0-7: no clinically significant insomnia; 8-14 subthreshold insomnia; 15-21: moderate insomnia; 22-28: severe insomnia). Generalized linear models were used to map the seven ISI items (Model 1), the ISI summary scores (Model 2), and the four ISI clinical categories (Model 3) onto EQ-5D utilities. Predictions were estimated using 50/50 split sample validation. Model fits were assessed using mean squared error (MSE) and distributional quality of predicted values. **RESULTS:** Respondents (n=2,842) were predominantly middle-aged, female, Caucasian, with ≥1 comorbidity. Mean sleep duration was 7.8 (±1.9) hours, mean ISI score was 14.1 (±4.8). Mean predicted utilities were (0.765±0.08) across all models, overlapping with observed utilities (0.765±0.18). Using Model 1, predicted utilities increased linearly with improving ISI (0.493 if ISI=28; 1.00 if ISI=0, p<0.01). In Model 2, each unit decrease in ISI summary was associated with a 0.022 (p<0.001) increase in utility. Predicted utilities were 0.868, 0.809, 0.722 and 0.579 for no clinical, sub-threshold, moderate and severe insomnia, respectively (Model 3). The overall MSEs between predicted and observed utilities were good in all models (Model I: 0.025, Model II & III: 0.026), especially when predicting utilities >0.40 (MSEs: 0.016-0.056). MSEs were higher when predicting lower utilities (MSEs: 0.138-0.156). **CONCLUSIONS:** Linear relationships were found between EQ-5D utilities and the ISI. These relationships can be used to estimate the impact of insomnia-associated treatment effects on utilities.

PND35

CREATION OF A WEB-BASED MULTIPLE SCLEROSIS PATIENT-REPORTED OUTCOMES RESEARCH PROGRAM

Deering K[1], Agarwal SS[2], Rajagopalan K[2], Harshaw Q[1], Shillington AC[1]
[1]*EPI-Q, Inc., Oak Brook, IL, USA,* [2]*Biogen Idec, Wellesley, MA, USA*

OBJECTIVES: To create and implement a secure web-based research program that collects and tracks validated patient-reported outcomes (PROs) for multiple sclerosis (MS) patients and their healthcare providers (HCP). **METHODS:** The *My MS Health* program can be accessed through a HIPAA secure website, www.mymshealth.org. A pilot study to evaluate the *My MS Health* program has been IRB-approved. Assessment of inclusion/exclusion criteria, enrollment, and informed consent with an electronic signature occurs through this secure website. Enrolled patients are prompted to complete a series of nine validated PRO surveys that measure MS specific symptom status, functional status, and quality-of-life, and results are immediately available. Patients may elect to give their HCP access to their real-time PRO results electronically. Aggregate data analysis can also be performed on the collected PRO data. **RESULTS:** In this ongoing study, 927 patients were enrolled and 122 were eligible to participate in the program evaluation survey at three months. Scores were measured on 5-point Likert scales with a range of low agreement (1) to high agreement (5) and scores greater than or equal to 3 signify agreement. Overall, 93% felt the amount of time it took to answer the surveys was just right, and 91% felt the website was easy to use (4.5+1.05). In addition, 92% reported they would likely continue participating in the program (4.08+1.11) and 78% reported they would likely recommend *My MS Health* to others (3.85+1.48). **CONCLUSIONS:** Preliminary results indicate *My MS Health* is an efficient and user friendly technology platform that patients will continue to use. Future evaluations will assess the impact of using the program on patient and HCP communication.

PND36

INTERNAL LOCUS OF CONTROL AND TREATMENT SATISFACTION WITH NATALIZUMAB

Stephenson JJ[1], Kern DM[1], Agarwal SS[2], Kamat SA[1]
[1]*HealthCore, Inc., Wilmington, DE, USA,* [2]*Biogen Idec, Wellesley, MA, USA*

OBJECTIVES: To assess the relationship between internal locus of control (ILOC) and treatment satisfaction in MS patients after 1 year of natalizumab treatment. **METHODS:** MS patients completed the Treatment Satisfaction Questionnaire for Medication (TSQM) prior to natalizumab initiation (BL) and after the 12th natalizumab infusion. Effectiveness, Convenience and Global Satisfaction subscale scores range from 0 to 100; higher scores indicate higher satisfaction. ILOC was assessed at BL and after the 12th infusion using the ILOC subscale of the Multidimensional Health Locus of Control questionnaire. Subscale scores range from 6 to 36; higher scores indicate greater ILOC. Correlation analysis and regression models evaluated the relationship between ILOC and satisfaction with natalizumab after 12 infusions, controlling for BL patient characteristics. **RESULTS:** A total of 333 patients (mean age 46.8+10.4 years and median of 9 years since MS diagnosis) completed all assessments. BL and 12th ILOC was correlated with BL and 12th Global Satisfaction (r=0.13, p=0.0247 and r=0.27, p<0.0001, respectively) and Effectiveness (r=0.23, p<0.0001 and r=0.29, p<0.0001, respectively); 12th ILOC was correlated with 12th convenience (r=0.12, p=0.0373). Regression model results showed that, after controlling for covariates, higher ILOC predicted greater global satisfaction (p=0.003), effectiveness (p=0.001) and convenience (p=0.017) with natalizumab after 12 infusions. **CONCLUSIONS:** Patients with MS with stronger internal beliefs about having control over their own health have higher satisfaction with natalizumab treatment after 12 infusions. Interventions supporting and reinforcing patients' health beliefs may have a positive impact on overall treatment satisfaction resulting in improved treatment adherence.

PND37

INVESTIGATION OF THE PSYCHOMETRIC PROPERTIES OF THE SHORT PARKINSON'S EVALUATION SCALE/SCALES FOR OUTCOMES IN PARKINSON'S DISEASE (SPES/SCOPA)

Buck PO[1], Conner JB[1], Castelli-Haley J[1], Wilson RE[2], Seeberger LC[3]
[1]*Teva Neuroscience, Kansas City, MO, USA,* [2]*Brentwood Neurology, Brentwood, TN, USA,* [3]*Idaho Elks Rehabilitation Hospital, Nampa, ID, USA*

OBJECTIVES: The Short Parkinson's Evaluation Scale/Scales for Outcomes in Parkinson's disease (SPES/SCOPA) was developed as a reliable and valid scale to evaluate motor impairment in Parkinson's disease (PD) patients and can be completed in less time than the gold standard Unified Parkinson's Disease Rating Scale (UPDRS). This study aimed to further investigate the reliability and validity of the SPES/SCOPA motor clinical examination, as relatively little research in the US has done so. **METHODS:** The BRAVURA study was designed to investigate order effects associated with the UPDRS motor examination at 2 centers in the US. Patients, stratified by center and previous Hoehn and Yahr (H&Y) stage, were randomly assigned to 1 of 2 UPDRS item sequences. All scale evaluations occurred during a single clinic visit. In addition to the 8-item SPES/SCOPA motor clinical examination and the 14-item UPDRS motor examination, scales included current H&Y stage and patient- and physician-rated Schwab and England Activities of Daily Living (ADL). Data were analyzed using Cronbach's alpha and Spearman's correlation. **RESULTS:** Complete data were available for 112 patients (mean time from diagnosis = 6.4 years). Relationships among the scales were comparable across the 2 experimental groups, thus data were pooled for these analyses; SPES/SCOPA mean score = 9.5 (SD = 5.2). The SPES/SCOPA demonstrated good internal reliability (alpha = 0.79). Construct validity was supported with the SPES/SCOPA correlating 0.76 with the UPDRS. Furthermore, the SPES/SCOPA correlated 0.47 with current H&Y stage and −0.39, −0.45 with patient- and physician-rated ADL, respectively. **CONCLUSIONS:** In this US sample of PD patients with varied disease severity, the SPES/SCOPA exhibited good psychometrics, including evidence of construct validity with the current standard of motor impairment measurement. The SPES/SCOPA also had good internal consistency and correlated with 3 broad evaluations of disease disability in a similar fashion to the UPDRS.

PND38

THE HIDDEN TOLL OF CAREGIVER BURDEN IN MULTIPLE SCLEROSIS

Stewart M[1], Phillips A[2], Edwards N[3], Gupta S[4], Goren A[5]
[1]*Pfizer, Inc., New London, CT, USA,* [2]*EMD Serono, Inc., Rockland, MA, USA,* [3]*Health Services Consulting Corporation, Boxborough, MA, USA,* [4]*Kantar Health, Princeton, NJ, USA,* [5]*Kantar Health, New York, NY, USA*